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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,292	11/13/2001	David James Squirrell	41577/266329	5898

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EXAMINER

LEARY, LOUISE N

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,292

Applicant(s)

SQUIRRELL ET AL.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1. Claims 1-23 are pending in this application.
2. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the metes and bounds intended for the phrase "particular conditions" cannot be determined.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim 21 is indefinite because the metes and bounds intended for the phrase "...effecting a method according to claim 1..." cannot be determined. Alternatively, "effecting a method" is ambiguous. It is suggested that "effecting" be changed to ---performing--- to distinctly claim the subject matter claimed in the present invention.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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(I) Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Squirrell (US 5,648,232) in view of Webster's Dictionary (1984).

Squirrell discloses a method for detecting the presence and/or amount of microorganisms and/or its intracellular material present in a sample. Squirrell discloses performing the method by "...estimating the amount of adenylate kinase therein by its ability to convert adenosine diphosphate (ADP) to adenosine triphosphate and relating that to the presence and/or amount of microorganisms and/or their intracellular material. This conversion is enabled by adding ADP to samples. Adenosine triphosphate (ATP) is preferably detected by use of the luciferin/luciferase system to provide a photometrically detectable signal indicative of the amount of ATP in the sample." See column 1, lines 62-68 and column 2, lines 1-9. With respect to detecting ATP in the sample and relating that to the presence of lysed cells, Squirrell discloses adding detergents to the samples evaluated in the assay methods. See column 11, lines 32-68 and column 12, lines 11-16. The use of detergents in enzymatic assay methods for lysing microbial cells was well known in this art at the time this invention was made. Also, Squirrell discloses and addresses reaction conditions and environmental factors used in the enzymatic assay methods. See column 15, lines 15-68 and column 16, lines 1-68. Regarding the use of eukaryotic cells in enzymatic assay methods, Squirrell discloses "All living organisms utilize adenosine triphosphate (ATP) as a source of chemical energy and it is known to assay this using the ATP driven luciferase/luciferin reaction. Light generated by this enzymic reaction can be measured using a luminometer and related to the amount of ATP present." See column 1, lines 15-19. Thus, Squirrell discloses the invention claimed except for addressing the use of eukaryotic cells.

However, with respect to addressing the use of eukaryotic cells in the instant assay method, Webster's Dictionary defines "microorganism" as "an animal or plant of microscopic size, esp. a bacterium or protozoan." Webster's Dictionary also defines "eukaryote" as "an organism having one or more cells with well-defined nuclei". It is noted that persons having ordinary skill in this art at the time this invention was made included viable nucleated cells in the definition of "microorganism". Therefore, Webster's definition of "microorganism" encompasses the eukaryotic cells in the sample of the present invention.

Hence, Squirrell discloses the invention claimed except for specifically addressing the use of eukaryotic cells in an enzymatic assay method, but, provides a general description of the use of the assay method for determining ATP in all organisms. In addition, Webster's definition of "microorganism" encompasses the definition of eukaryotic cells or eukaryote organisms. Thus, the Squirrell disclosure in view of Webster's Dictionary definitions of "microorganism" and "eukaryote" renders obvious the assay methods and kits of the present invention.

It would have been obvious to one having ordinary skill in this art at the time this invention was made to provide an enzymatic assay method and kit for performing the assay method as claimed in the present invention because Squirrell discloses the invention claimed except for specifically addressing the use of eukaryotic cells in an enzymatic assay method, but, generally describes the use of the assay method for determining ATP in all organisms and Webster's definition of "microorganism" encompasses the definition of eukaryotic cells or eukaryote organisms which previously provided sufficient guidance to make the invention claimed herein. Therefore, the Squirrell disclosure in view of Webster's Dictionary definitions of "microorganism" and "eukaryote" previously rendered the present invention obvious.

4. (II) Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Squirrell (US5,798,214) in view of Webster's Dictionary (1984).

Squirrell discloses a method for detecting the presence and/or amount of microorganisms and/or its intracellular material present in a sample. Squirrell discloses performing the method by "...estimating the amount of adenylate kinase therein by its ability to convert adenosine diphosphate (ADP) to adenosine triphosphate and relating that to the presence and/or amount of microorganisms and/or their intracellular material. This conversion is enabled by adding ADP to samples. Adenosine triphosphate (ATP) is preferably detected by use of the luciferin/luciferase system to provide a photometrically detectable signal indicative of the amount of ATP in the sample." See column 1, lines 7-68; column 2, lines 16-68; and column 3, lines 1-42. With respect to detecting ATP in the sample and relating that to the presence of lysed cells, Squirrell discloses adding detergents to the samples evaluated in the assay methods. See column 7, lines 5-21. The use of detergents in enzymatic assay methods for lysing microbial cells was well known in this art at the time this invention was made. Also, Squirrell discloses and addresses reaction conditions and environmental factors used in the enzymatic assay methods. See columns 2-7, lines 1-68 and columns 9-10. Regarding the use of eukaryotic cells in enzymatic assay methods, Squirrell discloses "All living organisms utilize adenosine triphosphate (ATP) as a source of chemical energy and it is known to assay this using the ATP driven luciferase/luciferin reaction. Light generated by this enzymic reaction can be measured using a luminometer and related to the amount of ATP present." See column 1, lines 19-23. Thus, Squirrell discloses the invention claimed except for addressing the use of eukaryotic cells.

However, with respect to addressing the use of eukaryotic cells in the instant assay method, Webster's Dictionary defines "microorganism" as "an animal or plant of microscopic size, esp. a bacterium or protozoan." Webster's Dictionary also defines "eukaryote" as "an organism having one or more cells with well-defined nuclei". It is noted that persons having ordinary skill in this art at the time this invention was made included viable nucleated cells in the definition of "microorganism". Therefore, Webster's definition of "microorganism" encompasses the eukaryotic cells in the sample of the present invention.

Hence, Squirrell discloses the invention claimed except for specifically addressing the use of eukaryotic cells in an enzymatic assay method, but, provides a general description of the use of the assay method for determining ATP in all organisms. In addition, Webster's definition of "microorganism" encompasses the definition of eukaryotic cells or eukaryote organisms. Thus, the Squirrell disclosure in view of Webster's Dictionary definitions of "microorganism" and "eukaryote" renders obvious the assay methods and kits of the present invention.

It would have been obvious to one having ordinary skill in this art at the time this invention was made to provide an enzymatic assay method and kit for performing the assay method as claimed in the present invention because Squirrell discloses the invention claimed except for specifically addressing the use of eukaryotic cells in an enzymatic assay method, but, generally describes the use of the assay method for determining ATP in all organisms and Webster's definition of "microorganism" encompasses the definition of eukaryotic cells or eukaryote organisms which previously provided sufficient guidance to make the invention claimed herein. Therefore, the Squirrell disclosure in view of Webster's Dictionary definitions of "microorganism" and "eukaryote" previously rendered the present invention obvious.

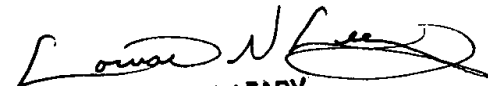
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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

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LOUISE N. LEARY
PRIMARY EXAMINER

February 13, 2003